REMARKS/ARGUMENTS

Prior to the present Office Action, claims 1-37 and 60-80 were pending (though claims 12-16, 19, 25 and 71-74 were previously withdrawn subject to allowance of the generic claims). Claims 86 and 87 have been added, and therefore claims 1-37, 60-80, and 86-87 remain pending.

The undersigned wishes to thank Examiner Thanh for a productive telephonic interview on August 27, 2003 during which various claims were discussed and clarification of the Examiner's previous Office Action was obtained.

Allowable claims

Applicants acknowledge the allowability of Claims 30-37 pending correction of the section 112 rejections, which are addressed below.

Drawing Objection

In the Office Action, the drawings were objected to under 37 CFR §1.83(a) for not showing a feature believed to be in claim 30. As discussed in the interview and explained below, the sheath having a device lumen and at least one auxiliary lumen is described and shown in the current specification and therefore no change to the drawings is believed necessary.

Specification Objection

The specification is objected to under 37 CFR §1.75(d)(1) for failing to provide proper antecedent basis for the same feature believed to be in claim 30. Again, the clarifying amendment to claim 30 is believed to obviate this rejection.

New Matter Objection

The previous amendment is objected to under 35 U.S.C. §132 for allegedly adding new matter; specifically, the term "an outer lumen having a particular location along its length having a cross-section which does not fully collapse during insertion into the body" was deemed not

supported by the original disclosure. Applicants assert that this term is fully supported by the original disclosure, but have nevertheless removed it to facilitate prosecution. No new matter is present in the application.

Section 112 Rejections

Claims 1-11, 17-18, 20-24, 26-29, 60-70, 75-76, and 77-80, stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner is of the opinion that the term an outer tube "having a cross-section which does not fully collapse during insertion into the body" was not described in the specification in a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully disagree, and assert that one of skill in the art would understand from the specification that the outer tube of the disclosed multiple lumen axis device does not fully collapse upon insertion into the body. Indeed, please see Fig. 24 and corresponding discussion which shows a multiple lumen access device of the present invention in place in the vasculature of a patient. In any case, however, this rejection is now moot because independent claims 1 and 60 have been amended to remove the objectionable term. These claims now state that the outer tube (or elongated body) is relatively stiff in relation to the flexible wall to facilitate introduction of the outer tube into a human body. Support for this language can be found at page 17, line 8, page 21, lines 16-20, and page 27, lines 20-24. Therefore, the section 112 rejection of claims 1 and 60 and their dependents is believed to be overcome.

Claims 30-37 stand rejected under 35 U.S.C. §112, second paragraph as being indefinite. Specifically, claim 30 is deemed to be indefinite because of the term "sheath defining within a device lumen." The relative clarity of this term was discussed in the interview, and Applicants have amended claim 30 as indicated above to render it more definite and to obviate the section 112 rejection. The "sheath" is believed to be adequately described in the specification, for example, in the first paragraph on page 19 as follows:

> The sheath portion of the devices of the present invention comprise the portion

that is distally disposed with respect to the junction housing, defines multiple lumens therein, and is substantially inserted into the patient's vasculature. In FIG. 13, the sheath portion 340 comprises an outer tube 342 defining within, and, in series from left to right, a device lumen 344, a first auxiliary lumen 346, and a second auxiliary lumen 348.

Therefore, the sheath is shown in the drawings, for example in Figure 13, the amendment to claim 30 is believed to clarify this, and no changes to the drawings are believed necessary.

Discussion of Martin

Claims 1, 3, 4, 21, and 28 stand rejected under 35 USC §102(b) as being anticipated by Martin (USPN 4,451,252). Martin discloses a dual lumen hemodialysis cannula having a peripheral generally cylindrical wall 28 with a septum 34 therein dividing the peripheral wall into two lumens 36, 38 (see figures 3-7). The septum 34 is deformed at the tip of the device by a fabrication mandrel in the manner shown in figures 3-6. More particularly, the septum 34 is deformed at the tip so it is sealed to the inner surface of the peripheral wall, thus closing off one of the lumens 38 at the tip. Side holes 68 in the peripheral wall allow blood ingress from a surrounding vein into the lumen 38, while treated blood is returned to the patient through the lumen 36 and out of the distal tip of the device. There is no mention of movement of the septum 34, nor of its flexibility in the abstract or relative to the peripheral wall 28. The entire "integrally formed" cannula "is inherently flexible and therefore may conform to the shape of the subclavian vein... " (col. 2 lines 54-56) In addition, there is no mention of passing devices through the cannula.

Claim 1, the other hand, provides for a combination device possessing the features of both introducer and multiple lumen catheter. Claim 1 provides an outer tube having an internal flexible wall (or walls) defining variably sized device and auxiliary lumens. The wall is sufficiently flexible to be movable from a first position, where the device lumen has a first cross-sectional area, to multiple flexed positions. Furthermore, claim 1 has been amended to specify that the outer tube is relatively stiff in relation to the flexible wall. Martin discloses a hemodialysis cannula not an introducer and multiple lumen catheter, the "septum 34" of Martin is not disclosed as nor

intended to be flexible and capable of moving positions, and there is no discussion in Martin of the relative stiffness of the peripheral wall and septum (indeed, the deformed septum at the distal tip stiffens the cannula for insertion into the body). Therefore, Applicants assert that claim 1 is neither disclosed nor taught by Martin. Moreover, dependent claims 3, 4, 21, and 28 provide further features not shown in Martin, most notably those pertaining to the flexible wall.

Discussion of Palestrant

Applicants gratefully acknowledge the Examiner's indication that the previous rejection under Palestrant (USPN 5,472,418) had been overcome in view of arguments filed April 30, 2002. However, in the interview of August 27, 2003, the Examiner appeared to suggest that removal of the claim language above pertaining to the "non-fully collapsible" outer tube might necessitate a further review of Palestrant. Applicants urge the Examiner to recall the arguments filed April 30, 2002 which were sufficient to overcome Palestrant, and to apply those arguments again for the present claims. Although the language pertaining to the collapsability of the outer tube has been removed, both claims 1 and 60 now specify that the outer tube is relatively stiff in relation to the flexible wall to facilitate introduction of the outer tube into the human body. An outer "tube" that has a certain stiffness that permits it to be introduced into the human body cannot be fully collapsible. And therefore, the same reasoning used by the Examiner in the previous analysis should carry over.

In any event, Palestrant does not disclose anything but two or more flattened strips of flexible material attached along their side edges to form tubes which are fully collapsible. The following passages from Palestrant should clearly illustrate to the Examiner that the device disclosed therein does not have an outer tube that is relatively stiff with respect to inner flexible walls.

> Central catheters are usually passed into the subclavian vein, jugular vein, or into an antecubital vein at the elbow. Such central catheters may have single or multiple lumens, and are typically made from a relatively rigid plastic material with a standard, round cross-section, both to facilitate placement of the catheter into the vein and to prevent the catheter lumens from collapsing within the vein. Generally speaking these

catheters are constructed in such a way that the lumen or lumens extending therethrough retain their cross-sectional configuration unless an external mechanical force compresses the catheter. (Background, col. 1, lines 24-34)

The normally-flattened tube expands toward a generally oval shape, depending upon the rate of infusion, when fluid is infused into a blood vessel of a patient, thereby providing an open path for the infusion fluid. When the infusion procedure is terminated, the tube collapses back to a generally flattened configuration for lying adjacent a wall of the blood vessel. (col. 3, lines 26-32)

Suitable materials for forming strips 32 and 38 include strong but flexible plastic films, including those made of polyethylene, polyethylene teraphthalate, and polyvinyl chloride. In the preferred embodiment of the present invention, these plastic films are inelastic, although plastic films which exhibit elasticity might also be used. (col. 7, lines 22-27)

As noted above, it is desired to make the majority of tube 44 that lies within the vein fully collapsible. However, a catheter that has no rigidity is almost impossible to insert into a vein as compared with a catheter which has rigidity. Accordingly, another aspect of the present invention relates to the apparatus and method used to place such a fully collapsible catheter within a vein. One such apparatus and method is shown in FIGS. 1 and 3C, wherein catheter 20 is pre-loaded onto a cylindrical guide wire 50 that initially extends through normally-flattened tube 44 to rigidify tube 44 and to temporarily shape it into a generally oval shape for insertion into the vein of a patient. (col. 7, lines 39-50)

A second method of rigidifying the catheter for insertion avoids the need for a guide wire and instead uses a pressurized fluid to inflate tube 44 for purposes of insertion. ...The next step is to pressurize tube 44 with fluid to rigidify tube 44 and make it more oval. (col. 8, line 44, through col. 9, line 1)

The catheter of Palestrant is therefore floppy and must be externally stiffened to facilitate insertion into the body. Further, there is no discussion of making the outer tube stiffer than any of the inner walls. Therefore, for the reasons discussed above, claims 1 and 60 and their dependent claims are believed novel and nonobvious over Palestrant.

Withdrawn Claims

Claims 12-16, 19, 25 and 71-74 were previously withdrawn as being directed to a non-elected species. Applicants believe that generic claims 1 and 60 are now allowable and therefore request that these claims be reinstated and allowed.

New Claims

Claims 86 and 87 are deemed to be allowable. They are, respectively, previous claims 2 and 26, with the "fully collapsible" term taken out of previous claim 1 as requested by the Examiner. These claims were not rejected on the basis of Martin, the section 112 problem with regard to the objectionable term has been rectified by its removal, and they are patentable over Palestrant because that patent does not disclose a device lumen let alone a device lumen valve nor that the catheter can be made of different materials.

Conclusion

In accordance with the foregoing remarks and amendments, claims 1-37, 60-80, and 86-87 are believed to be in condition for allowance. If there is any further hindrance to allowance, the Examiner is encouraged to contact the undersigned by telephone.

Previously Submitted IDS

Applicants previously submitted a number of Information Disclosure Statements, two (2) of which (specifically those submitted on April 16, 2001 and August 22, 2001) has not been received back yet with the Examiner's signature. Applicants respectfully request a copy of those two (2) IDSs signed by the Examiner for Applicants' records. Copies of previous submissions are attached herewith for the Examiner's convenience.

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Respectfully submitted,

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Guy Cumberbatch, Reg. No. 30,114
c/o Lena Vinitskaya
Edwards Lifesciences LLC
Law Department
One Edwards Way
Irvine, California 92614
Telephone: (949) 250-6856
Facsimile: (949) 250-6850
Customer Number: 30452

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